

Application No.: 09/880,842  
Advisory Action dated March 15, 2004

Docket No.: A7542.0000/P001-D

**Amendments To The Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Currently amended) A method for diagnosing tumorigenicity in a human patient, comprising:
  - obtaining a breast tissue biological sample containing cells from said patient;
  - detecting the protein encoded by SEQ ID NO. 16 in said cells of said breast tissue biological sample;
  - determining the number of cells containing said protein in said sample; and
  - determining the ratio of cells containing said protein to the total number of cells in said biological sample, wherein a ratio greater than about 5% zero is indicative of tumorigenicity.
2. (Currently amended) The method of claim 1, wherein said breast tissue biological sample comprises a material selected from the group consisting of blood, serum, and plasma, nipple aspirate, cerebrospinal fluid, liver, kidney, breast, bone, brain, colon, lung, testes, or ovary.
3. (Original) The method of claim 1, wherein said patient has been diagnosed with cancer.
4. (Currently Amended) The method of claim 3, wherein said cancer is selected from the group consisting of breast, ovarian, kidney, bone, pancreatic, testicular, liver, brain, colon, lung, and skin cancer.
5. (Previously presented) The method of claim 1, wherein said protein is detected by immunostaining with an anti-human GP88 antibody.
6. (Previously presented) The method of claim 1, where said protein is detected by diagnostic imaging with an anti-human GP88 antibody.

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Claims 7 - 9 (Canceled).

10. (Original) The ~~method~~ method of claim 6 wherein said anti-human GP88 antibody is radiolabelled.

6 ~~11~~. (Original) The method of claim 5, wherein said antibody is labeled.

1 ~~12~~. (Original) The method of claim ~~10~~<sup>or 6</sup>, wherein said label is selected from the group consisting of biotin, enzymatic, radioisotopic, fluorescent, and chemical labels.

Claims 13-19 (Canceled).

20. (Previously presented) The method of claim 1, wherein said number of cells is determined by microscopic examination.

9 ~~21~~. (Previously presented) The method of claim 1, wherein said number of cells is determined by a technique selected from group consisting of FACS analysis, luminex detection, antibody microarray, digital scanner, and cell sorter.

Claims 22-23 (Canceled).

24. (Currently amended) The method of claim 1 [[23]] wherein said ratio is at least about 10%.

25. (Previously presented) The method of claim 1 [[24]] wherein said ratio is at least about 25%.

26. (Previously presented) The method of claim 1 [[25]] wherein said ratio is at least about 50%.

27. (Previously presented) A method of determining whether a human patient is resistant to the antineoplastic effects of antiestrogen therapy, comprising:

obtaining a breast tissue biological sample containing cells from said patient; and

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detecting the presence of the protein encoded by SEQ ID NO. 16 in said sample wherein the presence of said protein in a ratio of greater than about 5% of the cells of the sample is indicative of resistance to the antineoplastic effects of antiestrogen therapy.

28. (Currently amended) A method of determining whether a human patient is resistant to the antineoplastic effects of antiestrogen therapy, comprising:

obtaining a breast tissue biological sample containing cells from said patient;

detecting the protein encoded by SEQ ID NO. 16 in said cells of said breast tissue biological sample;

determining the number of cells containing said protein in said sample; and

determining the ratio of cells containing said protein to the total number of cells in said breast tissue biological sample wherein a ratio greater than about 5% zero is indicative of resistance to the antineoplastic effects of antiestrogen therapy.

15 29. (Currently amended) The method of claim <sup>13</sup>27, wherein said biological sample comprises a material selected from the group consisting of blood, serum, and plasma; urine, nipple aspirate, cerebrospinal fluid, liver, kidney, breast, bone, testes, brain, colon, lung, or ovary.

16 30. (Original) The method of claim <sup>13</sup>27, wherein said patient has been diagnosed with cancer.

17 31. (Currently amended) The method of claim <sup>16</sup>30, wherein said cancer is selected from the group consisting of breast, ovarian, kidney, bone, pancreatic, testicular, liver, brain, colon, lung, and skin cancer.

18 32. (Previously presented) The method of claim <sup>13</sup>27, wherein said protein is detected by immunostaining with an anti-human GP88 antibody.

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33. (Currently amended) The method of claim ~~27~~ <sup>18</sup> ~~[[32]]~~, where said protein is detected by diagnostic imaging with an anti-human GP88 antibody.

Claims 34 - 36 (Canceled).

37. (Original) The method of claim 33 wherein said anti-human GP88 antibody is radio labeled.

<sup>19</sup> 38. (Original) The method of claim ~~32~~ <sup>18</sup>, wherein said antibody is labeled.

<sup>20</sup> 39. (Original) The method of claim ~~38~~ <sup>19</sup>, wherein said label is selected from the group consisting of biotin, enzymatic, radioisotopic, fluorescent, and chemical labels.

Claims 40-44 (Canceled).

<sup>21</sup> 45. (Currently amended) The method of claim ~~28~~ <sup>14</sup> ~~[[27]]~~, wherein said number of cells is determined by a technique selected from group consisting of FACS analysis, luminex detection, antibody microarray, digital scanner, and cell sorter.

<sup>22</sup> 46. (Previously presented) The method of claim ~~28~~ <sup>14</sup> wherein said ratio is at least about 10%.

<sup>23</sup> 47. (Original) The method of claim ~~46~~ <sup>22</sup> wherein said patient is estrogen receptor positive.

<sup>24</sup> 48. (Original) The method of claim ~~46~~ <sup>22</sup> wherein said ratio is at least about 25%.

<sup>25</sup> 49. (Currently amended) The method of claim ~~48~~ <sup>24</sup> wherein said patient is estrogen receptor positive.

<sup>26</sup> 50. (Original) The method of claim ~~48~~ <sup>24</sup> wherein said ratio is at least about 50%.

<sup>27</sup> 51. (Original) The method of claim ~~50~~ <sup>26</sup> wherein said patient is estrogen receptor positive.

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<sup>27</sup>  
~~52~~. (Currently amended) The method of claim <sup>13</sup>~~27~~ wherein the ratio said  
amount is at least about 10%.

<sup>28</sup>  
~~53~~. (Original) The method of claim <sup>28</sup>~~52~~ wherein said patient is estrogen receptor  
positive.

<sup>30</sup>  
~~54~~. (Currently amended) The method of claim <sup>13</sup>~~27~~ <sup>13</sup>[[53]] wherein the ratio said  
amount is at least about 25%.

<sup>31</sup>  
~~55~~. (Currently amended) The method of claim <sup>30</sup>~~54~~ wherein said patient is  
estrogen receptor positive.

<sup>32</sup>  
~~56~~. (Currently amended) The method of claim <sup>13</sup>~~27~~ <sup>13</sup>[[55]] wherein the ratio said  
amount is at least about 50%.

<sup>33</sup>  
~~57~~. (Original) The method of claim <sup>32</sup>~~56~~ wherein said patient is estrogen receptor  
positive.

Claims 58-63 (Canceled).

<sup>34</sup>  
~~64~~. (Currently amended) A method for diagnosing tumorigenicity, comprising:  
  
obtaining a breast tissue sample containing cells from a patient;  
  
detecting the protein encoded by SEQ ID NO. 16 in said cells of said breast  
tissue sample by immunostaining with anti-human GP88 antibody;  
  
determining the number of cells containing said protein in said sample by  
microscopic examination; and

determining the ratio of cells containing said protein to the total number of cells  
in said breast tissue sample wherein a ratio of at least about 5% ~~1%~~ indicates tumorigenicity.

<sup>35</sup>  
~~65~~. (Original) A method of determining whether an estrogen receptor positive  
patient is resistant to the antineoplastic effects of tamoxifen, comprising:

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obtaining a breast tissue sample containing cells from said patient;

detecting GP88 in said cells of said breast tissue sample by immunohistochemical staining with anti-human GP88 antibody;

determining the number of GP88 positive cells in said sample by microscopic examination; and

determining the ratio of GP88 positive cells to the total number of cells in said biological sample wherein a ratio of at least about 10% indicates said patient is resistant to the antineoplastic effects of tamoxifen.

Claims 66-85 (Canceled).